

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

“Track One Cases”

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**DEFENDANT MALLINCKRODT’S MEMORANDUM IN SUPPORT OF ITS
MOTION FOR SEVERANCE OR A SEPARATE TRIAL**

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Mallinckrodt LLC, SpecGx LLC, and Mallinckrodt plc¹ (together, “Mallinckrodt”) hereby submit the following memorandum in support of their Motion for Severance or a Separate Trial.

INTRODUCTION

“A fair trial in a fair tribunal is a basic requirement of due process.” *In re Murchison*, 349 U.S. 133, 136 (1955). The seven-week mass trial planned for October 21 does not come close to meeting the basic constitutional guaranty of fairness. Two Plaintiffs will each try 11 novel claims for billions of dollars against at least 45 individual defendants consisting of differently situated pharmaceutical manufacturers, distributors, and pharmacies. Such a trial against “the industry” as a whole simply cannot comport with procedural due process, which requires *individual* justice for each defendant. A jury must analyze each defendant’s liability under each of the Plaintiffs’ theories individually. That task is impossible given the mountains of irrelevant (often inflammatory) evidence against other defendants that a jury will need to disregard during these individual inquiries. The restrictions of a time-limited mass trial also make it impossible for each defendant to put forward a defense that delves deeper than the cartoonish portrayal Plaintiffs will put forward based on a few inflammatory shreds of evidence.

This is particularly true for Mallinckrodt. After more than a year of discovery, it is clear that the evidence Plaintiffs intend to use against Mallinckrodt differs significantly both in quantity and substance from the evidence against other defendants. As discussed herein, Mallinckrodt almost exclusively manufactures *generic* opioid products (which it does not market to healthcare providers) and has limited visibility into the pharmaceutical supply chain.

¹ Mallinckrodt plc is an Irish company that is not subject to and contests personal jurisdiction. It is specially appearing to join this motion and does not waive and expressly preserves its personal jurisdiction challenge; pursuant to Plaintiffs’ representation before the Court, foreign parent companies’ participation in pretrial briefing does not prejudice their jurisdictional arguments.

However, a jury hearing *all* the evidence in this case as against *all* defendants—some of which is a far better fit to Plaintiffs’ theories of liability—will be tempted to lump defendants together and not consider the individual evidence against each defendant. And the critical exculpatory evidence Mallinckrodt would present will be lost in a sea of unrelated, and largely prejudicial, evidence. Moreover, Mallinckrodt will not only be defending itself against Plaintiffs’ claims, but also against the sometimes inconsistent trial strategies and potential “finger-pointing” of its co-defendants. This untenable situation will undoubtedly infringe on Mallinckrodt’s right to a fair trial and subvert the legal system’s commitment to individualized justice. Accordingly, this Court should sever the claims against Mallinckrodt or order a separate trial on these claims.

BACKGROUND

A. The Diverse Group of Defendants Named in the Complaints and Set to Participate in the Track-One Trial

Plaintiffs’ far-ranging complaints each set forth 11 causes of action that span thousands of paragraphs and hundreds of pages. By Plaintiffs’ own description, their claims boil down to two overarching theories: (1) “a marketing scheme,” whereby they allege manufacturer defendants disseminated false and misleading information about their FDA-approved opioid products; and (2) diversion “scheme,” whereby Plaintiffs allege that all defendants failed to undertake necessary measures to detect and prevent diversion of opioid medications into the illegal supply chain.

Plaintiffs bring these claims against 21 corporate defendant groups falling into three categories: manufacturers, distributors, and retail pharmacies. Among the manufacturer category, there are six distinct corporate families: Allergan/Actavis, Endo/Par, Janssen/J&J, Mallinckrodt/SpecGx, Purdue, and Teva/Cephalon/Actavis. Each of these families has a vastly different involvement in the manufacture, marketing, and sale of opioid products. Some manufacture branded products, which are promoted to healthcare providers; some manufacture

generic pharmaceuticals, which are not promoted to healthcare providers; some have manufactured branded opioids for decades; some have only entered the market in the past five to ten years.

The distributors (including the “big three,” AmerisourceBergen, McKesson, and Cardinal Health) and retail pharmacies are likewise differently situated from the diverse group of manufacturers. Most pertinently, these entities occupy a position in the pharmaceutical supply chain far closer to the point at which diversion allegedly occurs. Distributors and pharmacies know immediately where products are sold and how much is sold.² Manufacturers, to the extent they learn anything about downstream distribution at all, receive an incomplete picture through “chargeback data” (financial reconciliation data that distributors provide to manufacturers *after* the sale), which is both limited in scope and delayed in timing.³

B. Mallinckrodt Is Uniquely Distinct from its Co-Defendants

Mallinckrodt accounts for only a small fraction of the allegations in this massive consolidated case. Only 35 paragraphs of the 1,179-paragraph Cuyahoga and 39 paragraphs of the 1,138-paragraph Summit complaint even mention Mallinckrodt. And for good reason: Plaintiffs’ manufacturer claims focus on allegedly misleading promotion, but Mallinckrodt is primarily a *generic—i.e., non-promoting—opioid* manufacturer. Excluding methadone—an addiction treatment medicine—generic products accounted *for an average of 99.9%* of Mallinckrodt’s relevant direct sales between 2006 and 2017.⁴ Mallinckrodt does not promote its generic products to health care providers; nor does it employ sales representatives for those products or publish promotional materials for them.⁵

² See Buthusiem Rep. 3–4 (Dkt. 1939-5/1936-5). On first reference, citations to expert reports and deposition transcripts filed on the docket include the docket numbers (both sealed and public versions). See Appendix A.

³ Buthusiem Rep. 3–5.

⁴ Based on relevant direct sales and calculated as a share of dosage units. Nat’l Direct Sales Data (Dkt. 1898-4/1907-4) (slipsheet for MNK-T10007897646; which Mallinckrodt will submit in native format). During this time frame, the generic opioid products always accounted for *more than 99.7%* of relevant direct sales. *Id.*

⁵ G. Collier Tr. 253:13–19 (Dkt. 1961-4/1976-4).

Mallinckrodt has only two branded opioid products at issue in the complaints, Exalgo and Xartemis. These products comprised, on average, a vanishingly small 0.1%⁶ of Mallinckrodt's relevant direct sales between 2006 and 2017, and they only went on the market in 2010 and 2014, respectively—at a time when opioid prescriptions were declining.⁷ Furthermore, all promotional materials for these branded products were consistent with their FDA-approved labels and included the required black-box warning concerning the risks of addiction.⁸

With regard to suspicious order monitoring (“SOM”), Mallinckrodt has always maintained an active SOM program and has continually improved the program to address changing needs.⁹ Mallinckrodt's program has included, among other measures, screening new customers, monitoring all incoming orders, regularly meeting with customers, ensuring customers had valid DEA registrations, training employees on compliance measures, auditing both distributors and downstream pharmacies, and using chargeback data to prevent diversion.¹⁰ Indeed, Mallinckrodt was the first to inform the DEA about chargeback data, and has received positive feedback from the DEA stretching back more than a decade—with the DEA telling Mallinckrodt in 2010 that its SOM program was “the best” it had ever seen.¹¹ Tellingly, Plaintiffs' own SOM experts conceded that they were not claiming that Mallinckrodt's program was insufficient after 2012.¹²

⁵ G. Collier Tr. 253:13–19 (Dkt. 1961-4/1976-4).

⁶ *See supra* n. 4.

⁷ Macgowan Decl. Exs. 2–4.

⁸ *See, e.g.*, Macgowan Decl. Exs. 5–7.

⁹ Harper Dep. Tr. 157:9–158:8, 189:18–190:7 (Dkt. 1944-34/1957-34); Rausch Tr. 98:8–19 (Dkt. 1970-3/1983-21).

¹⁰ *See, e.g.*, Macgowan Decl. Ex. 8 (screening); Harper Tr. 59:1–61:24, 232:20–234:3 (monitoring orders); Spaulding Tr. 108:3–22 (Dkt. 1971-1/1984-19) (customer meetings); Harper Tr. 59:1–61:24 (DEA registration); Rausch Tr. 57:5–21 (same); Macgowan Decl. Ex. 9 (training); Rausch Tr. 130:12–25 (same); Harper Tr. 391:11–20 (downstream audits); Ratliff Tr. 59:10–21 (1970-1/1983-19) (same); Nov. 1, 2010 Mallinckrodt Ltr. to DEA St. Louis (Dkt. 1898-16/1907-16) (chargeback data); Nov. 1, 2010 Mallinckrodt Ltr. to DEA Albany Div. (Dkt. 1898-17/1907-17) (same).

¹¹ Macgowan Decl. Ex. 10.

¹² Rafalski Tr. 665:19–666:8; Whitelaw Tr. 938:9–13 (Dkt. 1972-7/1985-19).

C. The Impossibility of the Track-One Mass Trial

After more than a year of coordinated discovery, involving the production of tens of millions documents and nearly 600 depositions of over 500 witnesses, the two bellwether cases in Track One are scheduled for a single seven-week trial to begin on October 21, 2019, in which all 21 defendant groups will be tried together before a single jury. *See* Order (Dkt. 1598).

The jury will need to resolve *nearly 1,000* questions of law and fact¹³ to reach a verdict for each cause of action for each Plaintiff as against each of the 45 plus individual defendants. Indeed, Plaintiffs acknowledge that they “will be required to prove their claims against each individual defendant based on each defendant’s alleged wrongdoing.” Dkt. 2099 at 2. This will involve reviewing the evidence pertaining to each manufacturer defendant’s opioid products and promotional materials, and each of the defendants’ suspicious order monitoring system over a period spanning as many as 24 years. And evidence pertaining to a few defendants—*i.e.*, those who have heavily promoted their products, or who have been on the front lines of wholesale distribution—will undoubtedly dominate the trial.

LEGAL STANDARD

Federal Rule of Civil Procedure 20(a) allows defendants to be joined in one action if the “right to relief . . . arise[s] out of the same transaction, occurrence, or series of transactions or occurrences” and “any question of law or fact common to all defendants will arise in the action.” Under Rule 21, a court “may at any time, on just terms, add or drop a party” or “sever any claim against a party.” Rule 42(b) allows a court to order separate trials on one or more separate issues or claims.¹⁴ “The Court’s determination as to whether it should sever the claims of the plaintiffs

¹³ Each of the 11 causes of action contains anywhere from 1 to 7 elements—each of which must be resolved for *each* defendant against which they are alleged, leading to approximately 582 elements for the jury to resolve, many of which must be resolved for *each* Plaintiff, nearly doubling the questions posed to the jury to upwards of 1,000.

¹⁴ Federal Rule of Civil Procedure 20(b) likewise grants the Court power to order separate trials.

under Rule 21 or whether it should order separate trials under Rule 42 requires the same considerations.” *Morris v. Northrop Grumman Corp.*, 37 F. Supp. 2d 556, 580 (E.D.N.Y. 1999). Most notably, these considerations include “whether prejudice would be avoided if severance were granted.” Fed. R. Civ. P. 42(b); *Parchman v. SLM Corp.*, 896 F.3d 728, 733 (6th Cir. 2018).

ARGUMENT

Courts have long recognized that joint trials that try multiple, differently situated co-defendants together, while convenient, do “not present any advantages in the search for truth” and present “dangers of prejudice.” *See United States v. Sophie*, 900 F.2d 1064, 1083 (7th Cir. 1990). Mass trials like the one planned here introduce the risk of significant prejudice to an individual defendant who deserves individual justice rather than have its cause “lost in the shadow of a towering mass litigation.” *In re Brooklyn Navy Yard Asbestos Litig.*, 971 F.2d 831, 853 (2d Cir. 1992); *see also In re Welding Fume Prod. Liab. Litig.*, No. 1:03-cv-17000, 2006 WL 2869548, at *2 (N.D. Ohio Oct. 5, 2006) (same). And such resulting prejudice justifies either severance or a separate trial. *See Grayson v. K-Mart Corp.*, 849 F. Supp. 785, 789–91 (N.D. Ga. 1994); *cf. United States v. Delatorre*, 522 F. Supp. 2d 1034, 1049 (N.D. Ill. 2007) (discussing “the likely jury prejudice that could result” from this “mega-trial” in a RICO case against 14 defendants).

This prejudice also interferes with the right to a fair trial under the Due Process Clause. “The fundamental requirement of due process is the opportunity to be heard ‘at a meaningful time and in a meaningful manner.’” *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)); *see also Bankers Tr. Co. v. Bethlehem Steel Corp.*, 752 F.2d 874, 890 (3d Cir. 1984) (“Due process mandates that a judicial proceeding give all parties an opportunity to be heard on the *critical and decisive allegations* which go to the *core* of the parties’ claim or defense . . .”). This procedural due process right to be heard “in a meaningful manner” is eviscerated if defendant-specific facts are lost in mountains of irrelevant and inflammatory

evidence related to co-defendants. “While the efficient administration of justice is always an important consideration, fundamental fairness to every litigant is an even greater concern.” *Columbus-Am. Discovery Grp. v. Atl. Mut. Ins.*, 974 F.2d 450, 470 (4th Cir. 1992).¹⁵

Proceeding with the mass trial planned here will be extremely prejudicial to Mallinckrodt—depriving Mallinckrodt of its due process rights and justifying severance or a separate trial. *First*, the planned mass trial will inevitably confuse a jury as it will be impossible for a jury to determine whether the evidence presented against *Mallinckrodt* is sufficient to find *Mallinckrodt* liable. *Second*, the mountains of evidence against Mallinckrodt’s differently situated co-defendants is wholly irrelevant to the claims against Mallinckrodt. And all this evidence is not merely background noise. It consists of inflammatory materials and testimony that will taint the jury’s view of “the industry”—and thus, Mallinckrodt—and could result in a verdict grounded in “guilt by association.” *Third*, significant prejudice also results from 21 different trial strategies, some actually directly antagonistic to Mallinckrodt. *Lastly*, this resulting spillover prejudice cannot be remedied through limiting instructions. Rather, to avoid this blatant prejudice (not to mention misjoinder)¹⁶ and deprivation of the constitutional right to a fair trial, this Court must either sever the claims against Mallinckrodt under Rule 21 or order a separate trial under Rule 42.

I. A Single Seven-Week Trial for 21 Distinct Defendant Groups Will Undoubtedly Result in Jury Confusion and Prejudice.

“Severance is appropriate where a joint trial could lead to confusion of the jury.” *Costello v. Home Depot U.S.A., Inc.*, 888 F. Supp. 2d 258, 265–66 (D. Conn. 2012) (severance appropriate

¹⁵ Indeed, rather than draining tens of millions of dollars from the parties on a trial likely to be reversed on appeal, the goal of efficient resolution would be better served by separate trials from the beginning.

¹⁶ Due to the factual distinctions between Mallinckrodt and its co-defendants, Mallinckrodt has also been misjoined under Rule 20(a): Plaintiff’s causes of action do not arise out of the same transaction and occurrences—but rather they largely arise out of each co-defendants *separate* sales and marketing of opioid products—and do not share “common issues of law and fact.” *See supra* pp. 2–4. This alone can justify severance under Rule 21.

when evidence regarding “thirty-nine different plaintiffs . . . would be confusing to a jury”). “The human limitations of the jury system are especially tested during a lengthy trial.” *Delatorre*, 522 F. Supp. 2d at 1050. “Jurors become overwhelmed by the volume of evidence and numbed by its repetitiousness,” *United States v. Warner*, 506 F.3d 517, 523 (7th Cir. 2007), and the “sheer confusion” from trying multiple claims against numerous defendants can prejudice defendants, *Sophie*, 900 F.2d at 1083. For example, in *Cain v. Armstrong World Industries*, defendants in a massive “[t]ry-as-many-as-you-can-at-one-time” trial did not receive a fair trial because excessive irrelevant evidence left the jury with “the *impossible task* of being able to carefully sort out and distinguish the facts and law of thirteen plaintiffs’ cases that varied greatly in so many critical aspects.” 785 F. Supp. 1448, 1457 (S.D. Ala. 1992) (emphasis added).

So too here. Over the course of seven weeks, two separate Plaintiffs will *each* try to prove their 11 overlapping causes of action against at least 45 defendants. The jury would be faced with a similarly “impossible task” of keeping track of each defendant’s products, each defendant’s promotional and marketing practices, and each defendant’s monitoring of its opioid sales and then apply these diverse facts to resolve dozens of elements as to each defendant. As in *Cain*, this outcome plainly prejudices the defendants. Tellingly, Plaintiffs themselves have acknowledged the “risk that the jury will be overwhelmed” and have moved to sever eight of the defendants. Dkt. 2099 at 3. Of course, the same risk identified by Plaintiffs exists as to the remaining 37 plus defendants, and severing eight (mostly marginal) defendants does not begin to resolve that risk.

II. A Joint Trial Will Require the Introduction of Irrelevant and Inflammatory Evidence Bound to Severely Prejudice Mallinckrodt and Deprive it of a Fair Trial.

Of particular concern with massive joint trials, and acutely present here, is the extremely prejudicial effect of a jury’s inability “to keep track of which evidence applies to which defendant,” potentially applying irrelevant evidence concerning a particular co-defendant across the board—

in essence, “lumping all the defendants together.” *Sophie*, 900 F.2d at 1083; *see also Sidari v. Orleans Cty.*, 174 F.R.D. 275, 282 (W.D.N.Y. 1996) (“A lumping together of such claims, which amounts to guilt by association, would unfairly prejudice the defendants.”). In these situations, and particularly in complex cases involving many different defendants and with “significant differences between . . . claims against [co-defendants], there is a risk that trying all of Plaintiff[s]’ claims in a single trial could lead to guilt by association and spillover prejudice.” *Deskovic v. City of Peekskill*, 673 F. Supp. 2d 154, 171 (S.D.N.Y. 2009) (internal quotation marks omitted). After all, “[c]ommon sense tells us that as evidence with respect to [one defendant] cumulates, it can only work to the harm and prejudice of [other defendants],” resulting in a “spill-over” prejudice. *United States v. Tsanges*, 582 F. Supp. 237, 240–41 (S.D. Ohio 1984).

For example, in *Wells v. City of Dayton*, this Court’s sister district held that inflammatory evidence introduced during a joint trial that was relevant only to some defendants and irrelevant to co-defendants resulted in prejudice and therefore necessitated a separate trial. 495 F. Supp. 2d 793, 795 (S.D. Ohio 2006). In a case involving § 1983 claims against the chief of police, the City of Dayton, and two police officers, the officers moved for a separate trial because otherwise the plaintiff could introduce evidence against the City and the chief regarding *past* incidents of alleged misconduct by *other* police officers, wholly unrelated to the incident in question. *Id.* at 794–95. The court granted this request, explaining that “questions regarding the liability of those *individual* Defendants must be decided by the jury only on the facts of the *particular* encounter on which this case is based” and “any inconvenience or lack of economy which would flow from the necessity of conducting two trials would pale in comparison to the prejudice which would befall [the officers]” if the joint trial proceeded. *Id.* at 795–96. (emphasis added).

The same reasoning applies here. Like in *Wells*, the jury will be left to decide Mallinckrodt's liability based on a "torrent of information concerning the conduct of . . . other unrelated situations at other times." *See id.* at 795. For both Plaintiffs' theories (marketing and diversion), it is inevitable that "spillover" prejudice will occur: the jury will hear a mass of inflammatory evidence concerning other defendants, irrelevant to Mallinckrodt. And the exculpatory evidence specific to Mallinckrodt will be lost in the sea of this irrelevant evidence.

Marketing Theory: Plaintiffs' entire marketing theory depends on a given defendant actually making promotional statements about opioid products. If Mallinckrodt faced a *separate* trial on the marketing issue, a jury would merely hear that Mallinckrodt almost exclusively sells generic opioid products and has *never* promoted the efficacy or use of those products to healthcare providers. A jury would further learn that the limited promotional materials distributed by Mallinckrodt—beginning only *after* opioid prescribing had already begun to crest and only for a limited number of years—for *two* branded products (i) could not have contributed to or caused the increase in opioid prescribing and (ii) contained only accurate statements and prominently displayed an FDA-mandated "black-box" warning of addiction and abuse risks. A Mallinckrodt-only jury would be hard-pressed to find a single relevant promotional statement made by Mallinckrodt, let alone any misrepresentation, that could serve as the basis of Plaintiffs' claims (or, for that matter, a single medically unnecessary prescription resulting therefrom).

However, the jury deciding Mallinckrodt's fate if the planned joint trial goes forward will not just hear and see the foregoing evidence, but instead will be inundated with inflammatory evidence from the five other manufacturer groups, some of which have been promoting opioids for more than two decades. Indeed, Plaintiffs' complaints indicate that their evidence will largely center around Purdue and OxyContin. *See, e.g.,* Cuyahoga Comp. ¶ 119 (1630/1631); Summit

Compl. ¶ 131 (Dkt. 1465/1466). Further, the jury will likely hear and see the following inflammatory evidence from other manufacturers (not Mallinckrodt), all of which is wholly irrelevant (and therefore prejudicial) to Mallinckrodt:¹⁷

- An internal communication, dating back to 1995, allegedly recommending that a manufacturer, not Mallinckrodt, show that one of its opioids had a lower risk of abuse than other narcotics to increase sales, *see* Cuyahoga Compl. ¶ 137; Summit Compl. ¶ 149;
- A 1996 memo in which a regional manager of a manufacturer, not Mallinckrodt, allegedly instructed representatives to inform physicians that there is “no[] upward limit” for dosing, Cuyahoga Compl. ¶ 241; Summit Compl. ¶ 253;
- A 2017 FDA press release allegedly requiring the removal of an opioid product (not Mallinckrodt’s) from the market “due to the public health consequences of abuse” and evidence that the manufacturer knew that “newer statistics around abuse and diversion are not favorable to [this] product” in 2011, Cuyahoga Compl. ¶¶ 150, 307; Summit Compl. ¶¶ 162, 319;
- An FDA warning letter to a manufacturer, not Mallinckrodt, for allegedly “representing that [an opioid] ‘was useful in a broader range of conditions or patients than has been demonstrated by substantial evidence,’” Cuyahoga Compl. ¶ 151; Summit Compl. ¶ 163;
- An FDA warning letter to a manufacturer, not Mallinckrodt, allegedly describing an opioid product’s “Internet advertisement as misleading” and “criticiz[ing] . . . other direct . . . advertisements” for not disclosing risks, Cuyahoga Compl. ¶ 836; Summit Compl. ¶ 790.

Each of the relevant defendants will surely dispute those allegations, but a mass trial nonetheless presents fertile ground for “guilt by association,” and Mallinckrodt will undoubtedly be prejudiced by the “spillover” of this irrelevant evidence.

Diversion Theory: A Mallinckrodt-only trial on diversion issues would reveal: (i) the DEA’s quota program authorized the amount of opioids Mallinckrodt produced; (ii) the DEA, through its ARCOS system, had access to each link in the opioid supply chain;¹⁸ (iii) the DEA has repeatedly lauded Mallinckrodt’s SOM program; (iv) Plaintiffs’ experts have *explicitly denied* holding the opinion that Mallinckrodt’s SOM program was in any way inadequate after 2012; and (v) Plaintiffs have not identified a single order that Mallinckrodt shipped to any customer that any

¹⁷ Mallinckrodt has no position on this evidence, but merely notes that Plaintiffs would likely proffer it at trial.

¹⁸ Buzzeo Rep. 7–8, 9 (Dkt. 1939-6/1936-6).

witness says Mallinckrodt should not have shipped (nor a single shipment that Mallinckrodt even made into Cuyahoga or Summit County in the last 20 years).

But in the planned mass trial, Mallinckrodt will be prejudiced by the following spillover evidence concerning other defendants' suspicious order monitoring and anti-diversion programs:

- A discussion of a settlement that a big three distributor entered based on, inter alia, allegedly delivering, in less than two years, more than 3 million doses of hydrocodone to one small pharmacy in Baltimore, Maryland without reporting any as suspicious, Pls.' Mem. Law Supp. CSA Mot. Partial Summ. Adj. 82 (Dkt. 1924-1/1910-1);
- Evidence that a different big three distributor did "not yet have a system for detecting all suspicious orders" as of 2008, and "had accumulated nearly \$1 billion in 'fines, settlements, and lost business' as a result of multiple regulatory actions" as well as documents suggesting "apathy toward regulatory compliance," *id.* at 69–71;
- Documents suggesting that a third big three distributor shipped orders even after it determined that the orders were suspicious and reported them to the DEA, *id.* at 94; and
- A manufacturer, not Mallinckrodt, had "*no SOM program whatsoever*" in place as recently as 2010, *id.* at 52.

Of course, Mallinckrodt has no visibility into the total shipments made by distributors nor other manufacturers' suspicious order monitoring decisions but will be extremely prejudiced by the need to defend itself against this cloud of irrelevant evidence.

III. Conflicting Defenses and Trial Strategies Will Also Prejudice Mallinckrodt.

Mallinckrodt will also be prejudiced by the joint trial here because its co-defendants will rely on conflicting defenses or trial strategies. *Cf. Golden Goose Deluxe Brand v. Aierbushe*, No. 19-cv-2518, 2019 WL 2162715, at *4 (S.D.N.Y. May 3, 2019); *WowWee Grp. Ltd. v. Meirly*, No. 18-cv-706, 2019 WL 1375470, at *6 (S.D.N.Y. Mar. 27, 2019). Defendants need not show that their defenses or strategies are *antagonistic* to establish prejudice, but only "that there is tension in their trial strategies"—*i.e.*, that "each defendant will emphasize certain factual distinctions" and such "contrasting factual distinctions" are both confusing to the jury and prejudicial to individual defendants. *Weiss v. Nat'l Westminster Bank PLC*, No. 05-cv-4622, 2017 WL 10058916, at *4 (E.D.N.Y. Mar. 31, 2017). For example, in *In re Repetitive Stress Injury Litigation*, the Second

Circuit vacated the consolidation of 44 cases that asserted claims for damages for “repetitive stress injuries” involving separate defendants, reasoning that the “aggregate litigation” caused prejudice because “defendants manufacture or distribute a variety of mechanical devices with differing propensities, if any, to cause the harm alleged.” 11 F.3d 368, 371–73 (2d Cir. 1993). And, such “[c]onsiderations of convenience and economy must yield to a paramount concern for a fair and impartial trial.” *Id* at 373 (internal quotation marks omitted).

The same risk of prejudice is created here: each of the 21 defendant families will presumably have its own trial strategy based on its own factual distinctions and defenses—*e.g.*, one defendant may have taken a certain approach to monitoring suspicious orders where others did not. Of course each defendants’ counsel will use these distinctions to set its own client apart from the rest. These varied strategies and distinctions will be confusing for the jury and prejudicial.

Worse still, the defenses here are not merely in “tension,” they are likely to be outright *antagonistic*. For example, the distributors have already explicitly tried to shift blame to the manufacturers, arguing that “Plaintiffs seek to impose liability on Distributors for *Manufacturers’ alleged marketing misconduct* based on civil conspiracy.” Mem. Supp. Distributors-Defs’ Civil Conspiracy Mot. Summ. J. 1 (Dkt. 1692/1908). Distributors apparently plan to point the finger at manufacturers, including Mallinckrodt, in an effort to escape their own potential liability. Prejudice and procedural due process violations are a given: Mallinckrodt will not only need to contend with attacks from the table to the left, but also from the attorney sitting to the right.

IV. Limiting Instructions Will Not Remedy the Infringement on Mallinckrodt’s Right to a Fair Trial.

“[T]here are some contexts in which the risk that the jury will not, or cannot, follow instructions is so great, and the consequences of failure so vital to the defendant, that the practical and human limitations of the jury system cannot be ignored.” *Bruton v. United States*, 391 U.S.

123, 135 (1968). Limiting jury instructions cannot cure the prejudice that will befall Mallinckrodt if it is tried together with dozens of differently situated defendants—again, including brand manufacturers that have been promoting opioid products for decades and distributors engaged in wholesale distribution of opioid products, many of whom will be pointing fingers at each other and Mallinckrodt to defend against their own liability. When co-defendants introduce inadmissible and either inflammatory, accusatory, irrelevant, or even large quantities of evidence during joint trials—as here—federal courts have recognized that limiting instructions cannot cure the risk of prejudice. *See, e.g., Costello*, 888 F. Supp. 2d at 266 (introducing evidence regarding 39 separate plaintiffs “could easily confuse a jury even with the clearest of jury instructions.”).

The “prime consideration” in whether limiting instructions will be effective to address the risk of prejudice is “whether the jury can reasonably be expected to compartmentalize the evidence” as to each defendant. *United States v. Gaines*, 563 F.2d 1352, 1355 (9th Cir. 1977). Where a jury cannot compartmentalize evidence, jury instructions will not protect the defendant from substantial prejudice. In *Moorhouse v. Boeing Co.*, for example, the court held that jury instructions would not cure the risk of prejudice resulting from trying six plaintiffs’ cases against 17 defendants in a single trial. 501 F. Supp. 390, 392, 393 n.4 (E.D. Pa. 1980). Notwithstanding factual overlap, “there were . . . substantial enough factual distinctions . . . which made it impractical to try all the cases to the same jury.” *Id.* at 392. The court was “convinced a jury would have faced a hopeless task of trying to discern who did and said what to whom and for what reason” and “*even the strongest jury instructions could not have dulled the impact of a parade of witnesses.*” *Id.* at 393 n.4 (emphasis added). Likewise, in *Weiss*, because most of the exhibits to be introduced were unique to a particular defendant (and irrelevant to the remaining defendants) and “weeks of defendant specific evidence [would] consume a consolidated trial,” the court

concluded that it could not instruct a jury to assess the liability of one defendant “by putting aside a significant amount of evidence introduced against another defendant on the same issue.” 2017 WL 10058916, at *3. This risk could not be remedied by either “continuous[]” limiting instructions or controlling the order in which different evidence is presented to the jury. *Id.*

So too here. There may be factual overlap regarding the legal claims, but the factual distinctions among the parties make the joint trial “impractical” and jury instructions futile. The jury for the planned mass trial will face a “hopeless task” of sorting out who promoted what drugs and when, whether those promotions contained misrepresentations, who heard those misrepresentations, and so on. It will need to grapple with different defendant groups’ different degrees of visibility into the supply chain. Even more, like in *Weiss*, it is inevitable that key defendants (those who feature prominently in the complaint and have been the main focus of discovery) will dominate the trial, requiring “continuous[]” limiting instructions. *See id.*

These precautionary measures simply cannot “undo the possible confusion” that would result from asking the jury to assess the evidence specific to Mallinckrodt and to “put[] aside” large swaths of evidence related to other key defendants. *See id.* And the factual distinctions among defendants are *critical* for Mallinckrodt: (i) as a generic manufacturer, it had limited involvement in marketing opioids and (ii) as a manufacturer, it had limited visibility into the supply chain (other than after-the-fact data) and therefore limited ability to monitor suspicious orders (as compared to the “big three” distributors and pharmacies). Regardless of “how carefully [the] jury [is] instructed as to separate consideration” for each defendant, there is a significant risk that a jury will be influenced, even “subconsciously,” by irrelevant, inflammatory evidence. *See Baker v. Waterman S.S. Corp.*, 11 F.R.D. 440, 440–41 (S.D.N.Y. 1951).

CONCLUSION

This Court should grant Mallinckrodt’s motion to sever claims or hold a separate trial.

Dated: August 5, 2019

Respectfully submitted,

/s/ *Brien O'Connor*

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LOCAL RULE 7.1(f) CERTIFICATE OF SERVICE

Pursuant to Local Rule 7.1(f), Mallinckrodt has 15 pages for non-dispositive motions. This memorandum adheres to the limits set forth in that order, as it totals 15 pages.

Dated: August 5, 2019

/s/ Brien T. O'Connor
Brien T. O'Connor

CERTIFICATE OF SERVICE

I, Brien T. O'Connor, hereby certify that the foregoing document was served via file transfer protocol and email to all counsel of record.

/s/ *Brien T. O'Connor*
Brien T. O'Connor

APPENDIX A

Deposition Transcripts	Date	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Collier, Ginger	01/08/19	Defendant	1961-4	1976-4
Harper, Karen	01/15/19	Defendant	1962-19	1957-34
Rausch, James	11/16/18	Defendant	1970-3	1983-21
Rafalski, James	05/14/19	Plaintiff	1969-19	1983-16
Spaulding, Eileen	02/05/19	Defendant	1971-1	1984-19
Whitelaw, Seth	05/17/19	Plaintiff	1972-7	1985-19

Expert Reports	Date	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Buthusiem, Edward	05/10/19	Defendant	1939-5	1936-5
Buzzeo, Ronald	05/31/19	Defendant	1939-6	1936-6

Other Documents	Date¹⁹	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Civil Jury Trial Order	05/01/19	Court Order	N/A	1598
Distributors' Civil Conspiracy Mot. Summ. Judg.	07/19/19	Defendant	1692	1908
MNK-T1_0007897646	07/19/19	Defendant	1898-5	1907-5
National Direct Sales Data	07/19/19	Defendant	1898-4	1907-4
Nov. 1, 2010 Mallinckrodt Ltr. to DEA Albany Div.	07/19/19	Defendant	1898-17	1907-17
Nov. 1, 2010 Mallinckrodt Ltr. to DEA St. Louis	07/19/19	Defendant	1898-16	1907-16
Pl. CSA Mot. Part. Summ. Adj.	07/19/19	Plaintiff	1924	1910
Pl. Mot. Part. Summ. Adj. of Their Equitable Claims for Abatement of an Absolute Public Nuisance	07/19/19	Plaintiff	1880	1890
Pl. Mot. to Sever Def.	07/31/19	Plaintiff	N/A	2099

¹⁹ Date refers to date filing appeared on the docket.